JAN 1 7 2003

SECTION 6 – 510(k) SUMMARY

K023535

Pg. 1 of 3

[Submitted pursuant to 21 CFR 807.87(h)]

1. Submitter Information

Submitter:	Direx Systems Corporation 11 Mercer Road Natick Business Park Natick, MA 01760
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Contact Person	Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade/Proprietary Name:	Tripter X-1 Compact Duet (to be marketed as "Tripter Duet" or "Duet")
Common/Usual Name:	Extracorporeal Shock Wave Lithotripter (ESWL)
Classification Name/ Product code:	78 LNS
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.5990

3. Predicate Devices

Tripter X-1 Compact: P920034

Storz Modulith SL-20/ (SLX): P920051

Storz SLK: K010340

PCK Stonelith V5: K011106

4. Intended Use:

Fragmentation of urinary tract stones (*i.e.* renal calyceal, renal pelvic, and upper ureteral stones).

5. Technological Characteristics:

The Duet is a modification of an existing device that enables the use of 2 reflectors instead of one. The modified device has the same fundamental scientific technology and intended use as predicate devices.

6. Description

The *Duet* is a transportable Electrohydraulic Extracorporeal Shock Wave Lithotripter, which consists of a Shock Wave Generator (SWAG), a Motorized Floating Treatment Table (MFT), and control means.
The Shock Wave Generator can be operated in 4 modes:

a) Bottom Reflector only.
b) Top reflector only.
c) Alternate mode (asynchronous).
d) Simultaneous mode (synchronous).

7. Performance Testing

The *Duet* Lithotripter was tested according to the following standards:

- IEC 60601-1(1988) +A1 (1991) +A2 (1995)
- IEC 60601-1-1 (2000)
- IEC 60601-2-36 (1997)
- IEC 60601-2-38 (1996) +A1 (1999)
- UL 2601-1-1997, CSA-C22.2 No. 601.1
- IEC 60601-1-2 (2001)
- CISPR 11(1997) + A1 (1999) class B
- IEC 606001-2-36 (1997), clause 36
- IEC 61846 (1998-04)
- IEC EN 1441
- IEC 60601-1-4 (2000)

8. Clinical Tests

No clinical tests were performed.

9. Conclusion

The *Duet* meets the requirements for a special 510(k) by the virtue of being a minor modification, which does not change the fundamental technology or reduce safety and effectiveness, of the Company's predicate device, the *Tripter X-1 Compact*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Larisa Gershtein
QA Manager
DiREX Systems Corp.
11 Mercer Road
NATICK MA 01760

JAN 17 2003

Re: K023535
Trade/Device Name: Tripter X-1 Compact Duet
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: December 19, 2002
Received: December 20, 2002

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4-1

DiREX SYSTEMS CORP.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023535

Device Name:

Tripter-X1 Compact Duet

Indications for Use:

The Tripter-X1 Compact Duet Extracorporeal Shock Wave Lithotripter is indicated for use in the fragmentation of urinary tract stones (i.e. renal calyceal, renal pelvic, and upper ureteral stones).

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K023535

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR § 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023535

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